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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 22 1994

Re: Zosyn®
Docket No. 94E-0071

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,562,073, filed by Taiho Pharmaceutical Company Ltd. under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zosyn®, the human drug product claimed by the patent.

The total length of the regulatory review period for Zosyn® is 1,819 days. Of this time, 1,038 days occurred during the testing phase and 781 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 31, 1988.

   The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received by the agency on June 14, 1988 and was placed on clinical hold July 1, 1988. It was removed from clinical hold on October 31, 1988, making the IND effective date October 31, 1988.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: September 3, 1991.

   The applicant claims August 30, 1991, as the date the new drug application (NDA) for Zosyn® (NDA 50-684) was initially submitted. However, FDA records indicate that NDA 50-684 was submitted on September 3, 1991.

3. The date the application was approved: October 22, 1993.

   FDA has verified the applicant's claim that NDA 50-684 was approved on October 22, 1993.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Robert B. Murray
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